REMARKS

Entry of the above amendments and reconsideration of this application are requested. Upon entry of the amendments, this application will contain claims 1-9, 11-16 and 18-50. Of these, claims1-9, 11-16 and 18-29 were examined in the Office Action. Claims 30-50 are new claims and are fully supported in the original claims and in the specification. Thus, these claims introduce no new subject matter.

Claims 1-9, 11-16 and 18-29, as prior pending, stand rejected under 35 U.S.C. 103(a) over Wironen et al. (U.S. Publication No. 2002/0076429). To the extent maintained against any of these claims as amended, or against any of the new claims, it is submitted that this rejection would be improper for the reasons detailed below. Accordingly, reconsideration and allowance of this application are solicited.

When rejecting claims under 35 U.S.C. § 103, "the Examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art." *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783 (Fed. Cir. 1992). To establish a prima facie case of obviousness, the Examiner must provide objective evidence 1) of some suggestion or motivation to combine or modify one or more prior art references, 2) that the suggested combination or modification has a reasonable expectation of success, and 3) that the prior art reference or references, when combined, suggest or teach all of applicant's claim limitations. MPEP § 2143. As held by the Federal Circuit, "[t]hese findings or evidence must be specific, clear, and particular." *In re Lee*, 61 U.S.P.Q. 2d 1430, 1433-34 (Fed. Cir. 2002). "Broad conclusory statements regarding the teaching of multiple references, standing alone, are not [considered sufficient] 'evidence' " to support a finding of prima facie obviousness. *In re Dembiczak*, 50 U.S.P.Q. 2d 1614, 1617 (Fed. Cir. 1999); See also, *Ex Parte Levengood*, 28 U.S.P.Q. 2d 1300, 1301 (Bd. Pat. App. & Int. 1993).

Obviousness determinations must be performed without "entry into the 'tempting but forbidden zone of hindsight.'" *Dembiczak*, 50 U.S.P.Q. 2d at 1616 (Fed. Cir. 1999). More specifically, in *Dembiczak*, the Federal Circuit offered the following guidance:

> [m]easuring a claimed invention against the standard established by section 103 requires the oft-difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. . . .

Dembiczak, 50 U.S.P.A. 2d at 1617. The best protection against the use of hindsight is a rigorous application of the motivation criterion, which results in most *prima facie* obviousness determinations hinging on an objective finding of some motivation or suggestion to combine or modify one or more prior art references. See, *Dembiczak*, 50 U.S.P.Q. 2d at 1617; *In re Roufett*, 47 U.S.P.Q. 2d 1453, 1457-58 (Fed. Cir. 1998).

It is likewise important to note in this context that in determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983) "[A] patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified. This is part of the 'subject matter as a whole' which should always be considered in determining the obviousness of an invention under 35 U.S.C. § 103." *In re Sponnoble*, 405 F.2d 578, 585, 160 USPQ 237, 243 (CCPA 1969).

When considered in a proper analysis under 35 U.S.C. 103, it is submitted that the present claims are nonobvious and therefore patentable in relation to the applied reference, Wironen et al. Illustratively, claim 1 is directed to an osteogenic paste composition that includes "a resorbable paste carrier comprising a macromolecular carrier material" in combination with "an osteogenic factor comprising a bone morphogenic protein, wherein said bone morphogenic protein is effective to stimulate both osteoblasts and osteoclasts when administered to a human, and wherein said bone morphogenic protein is incorporated into said paste composition in such an amount as to stimulate the osteoclasts sufficiently to cause an increase in the rate of resorption of the macromolecular carrier material when the paste composition is implanted in the human. The paste composition further includes "a porous particulate mineral in an amount of at least 20% by volume of the composition, said amount being effective to provide a scaffold for bone ingrowth as the resorbable paste carrier is resorbed." As disclosed in the present application, one feature of the invention:

> relates to the discovery that the inclusion of an osteoblast- and osteoclast-stimulating osteogenic factor in a paste-form composition including a resorbable paste carrier causes a rapid and premature resorption of the carrier. This rapid resorption of the carrier can diminish or eliminate the capacity of the paste-form composition to effectively stimulate and support new bone formation in a void filled with the composition. This particularly true in the case of primates, including humans, in which the rate of new bone formation is relatively slow.

See application, page 7, lines 6-14. This discovery pointed out in the application is supported by specific Examples set forth on pages 21-23. Accordingly, the claimed compositions and methods involve compositions that include a relatively high proportion (20% by volume or more) of a particulate mineral material along with the osteoclast- and osteoblast-stimulating osteogenic factor and resorbable carrier. Wironen et al. does not disclose the problem discovered by applicant, and only discloses the incorporation of mineral as an option, only generally disclosing potential ranges for incorporation of mineral, starting at zero. Wironen discloses absolutely no need or motivation for the necessary incorporation of relatively high levels of the mineral component when the bone morphogenic protein (an optional ingredient) is incorporated into the resorbable paste formulation. Only the applicant's discovery disclosed in the application points up this need; however, use of applicant's own specification in filling in the gaps left by the prior art would be an inappropriate use of hindsight in making the obviousness rejection.

As basis for the rejection made, the Office Action states that "It would have been obvious to one having ordinary skill in the art at the time of the invention was made to adjust the ratios of the carrier to other materials and particle sizes, since it has been held that where the general conditions of the claim are disclosed in the prior art discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233." However, the *Aller* case is inapplicable here. In *Aller*, the claims under consideration were to a chemical process for decomposing isopropyl benzene hydroperoxide to form phenol. The claims encompassed the use of temperature and sulphuric acid concentrations that differed from the prior art that resulted in an improvement that was "but a few percentage points different from the results reported by the reference". The court found the claims obvious because it said that temperature and concentration changes in such chemical processes generally were not patentable and because only slight changes in degree resulted from the claimed process.

To the contrary, the present case does not deal with chemical processes for producing phenol, or anything similar. The claims involve compositions and methods for generating bone, lying in the realm of biological reaction to implanted substances including bone morphogenic proteins and other components. As demonstrated by the Examples of the application, such biological reactions can be highly unpredictable, resulting or not resulting in significant bone formation. Moreover, as noted above, the claimed invention as a whole must be considered, and a patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified. *In re Sponnoble*, 405 F.2d 578, 585, 160 USPQ 237, 243 (CCPA 1969).

As to the method claims pending, it is noted that the Office Action considered them to relate to an "intended use of the composition" and thus gave the method steps no weight in considering the claims, citing *Ex parte Masham*, 2 USPQ 1964 (1987). However, this principle would be applicable, if at all, only in relation to composition claims, and not to method claims. When considering the patentability of method claims under 35 U.S.C. 103, all recited steps must be considered. As such, a fresh consideration of all method claims, giving weight to all recited steps, is solicited.

In view of the foregoing remarks, it is submitted that the application of the present rejection over Wironen to any of the claims presently pending would be in error. Reconsideration and allowance of this application containing claims 1-9, 11-16 and 18-50 are thus solicited. The Examiner is invited to contact the undersigned attorney if there are any questions about this submission or other matters that can be handled in that fashion to expedite the allowance of this application.

Respectfully submitted,

By _____
Kenneth A. Gandy
Reg. No. 33,386
Woodard, Emhardt, Moriarty,
McNett & Henry LLP
Chase Tower, Suite 3700
111 Monument Circle
Indianapolis, Indiana 46204-5137
(317) 634-3456